REMARKS

The Office Action mailed March 20, 2006, has been carefully reviewed. Claims 26 - 33 are newly added. Claims 15- 25 are canceled and claims 1-14 stand canceled. The amendments to the claims are to more precisely and distinctly claim the subject matter of the invention.

Claims 15 and 19 stand objected to for failure to recite the full meaning of "HCMV."

Claims 15, 18, and 20 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinte.

Claims 21, 23 and 25 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Gibson et al. (1984).

Claims 15 and 16 stand rejected under 35 U.S.C. § 103 as allegedly obvious over Michel et al. (1996) in view of Wang et al. (US 5,830, 727).

Claims 15, 17, and 18 stand rejected under 35 U.S.C. § 103 as allegedly obvious over Michel et al. (1996) in view of Wang et al. (US 5,830, 727) and further in view of Uyttersprot et al. (1998).

Claim 20 stands rejected under 35 U.S.C. § 103 as allegedly obvious over Michel et al. (1996) in view of Wang et al. (US 5,830, 727) and further in view of Irmiere et al. (1983).

Claims 21 and 22 stand rejected under 35 U.S.C. § 103 as allegedly obvious over Gibson et al. (1984) in view of Wills et al. (1996).

Claim 19 is deemed free of prior art of record and therefore allowable. Applicant gratefully acknowledges the Examiner's indication of allowable subject matter.

The claims as amended herein are fully supported by the application as originally filed. No new matter has been added. Reexamination, reconsideration, and allowance of the present application are respectfully requested in view of the foregoing amendments and the following additional remarks.

Information Disclosure Statement

The Examiner reminds the Applicant that listing of references in a specification is not a proper information disclosure statement. In response, Applicant points out that the current Application is a divisional of U.S. 09/914,948 (now Patent No. 6, 713, 070) and deems the Examiner to be aware of the references cited in the parent by way of Information Disclosure Statements. Nevertheless, for the Examiner's convenience, Applicant hereby re-cites those same documents in the accompanying Information Disclosure Statement and respectfully ask the Examiner to indicate their due consideration.

Objection to the Specification

The Examiner objects to the specification for failure to update the status of the parent priority application; for spelling error in the title; and for improper formalities with respect to appropriate use of trademarks.

In response, Applicant hereby amends the title and also encloses a substitute specification as Appendix A in which the above issues have been addressed and/or obviated. Additionally, Applicant also added Section Headers to more properly comply with U.S. formalities. No new matter has been added.

Claim Objections

Claims 15 and 19 stand objected to for failure to recite the full meaning of "HCMV." As is shown in new claim 26, this ground for objection is now obviated and its withdrawal is respectfully requested.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 15, 18, and 20 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinte for failure to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner asserts that claim 18 recites a trademark and thus renders it indefinite. Applicant respectfully disagrees. FuGENE® transfection protocol is a well-known proprietary protocol that uses a proprietary reagent, namely FuGENE® reagent. In this instance, the trademark itself is a "reagent" and not an item of indefinite composition. Moreover, the mark is used in such a manner that will enhance and not dilute the strength of the mark because the mark itself intrinsically describes a proprietary product and the claim merely states the use of that proprietary product as a limitation.

Under MPEP 608.01(v), if the product to which the trademark refers is set forth in such language that its identity is clear, the Examiner is authorized to permit the use of the trademark if it is distinguished from common descriptive nouns by capitalization. Having met the standards for allowable use of trademarks, it is respectfully requested that this ground for rejection be withdrawn.

The Examiner further asserts that claims 15 and 20 omitted essential steps. New claim 26 is essentially a combination of canceled claims 15 and 20, and said new claim 26 has incorporated the steps deemed to be omitted. This ground for rejection now moot, it is respectfully requested that it be withdrawn.

Rejections Under 35 U.S.C. § 102

Claims 21, 23 and 25 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Gibson et al. (1984).

The Examiner asserts that the instant claims read on viral particles, which are released after infection of mammalian cells with HCMV, and pharmaceutically acceptable carrier for formulation into a composition for immunization against HCMV diseases and infections. The Examiner further asserts that Gibson et al. teaches the isolation of dense bodies (DBs) and noninfectious enveloped particles (NIEPs) after infection of mammalian cells with HCMV and

their use as HCMV subunit vaccine candidates. The Examiner further asserts that Gibson et al. teaches that neither DBs nor NEIPs contain DNA but both contain all glycoprotein species present in virions, and that DBs lack all of the capsids.

Claims 21, 23 and 25 are now canceled, thus rendering this ground for rejection moot as to those claims. Amended claim 31 directed to a vaccine composition includes all the limitations of canceled claim 22 deemed by the Examiner to be free and clear of Gibson et al. For that at least, this ground for rejection is now obviated and its withdrawal is respectfully requested.

Rejections Under 35 U.S.C. § 103(a)

Claims 15 and 16 stand rejected under 35 U.S.C. § 103 as allegedly obvious over Michel et al. (1996) in view of Wang et al. (US 5,830, 727).

According to the Examiner, Michel et al., discloses an HCMV gene with the N-terminal region of UL97 deleted and the deleted HCMV is replicated in human foreskin fibroblasts and Wang et al. discloses the technique of isolation and propagation of deletion mutant Herpes Simplex Viruses in a cell line transfected with complementing levels of the deleted essential gene of the viruses.

While admitting that Michel et al. does not disclose transfected mammalian cell line which expresses the deleted HCMV gene so that the deleted HCMV can replicate in the cells, the Examiner nevertheless asserts that it would have been obvious to one of skill in the art to add the cell line transfected with complementing levels of deleted essential viral gene of Wang et al. to the methods of Michel et al. to improve the efficiency of HCMV replication. While not agreeing with the Examiner's characterization of the teachings of Michel et al. and Wang et al., Applicant asserts that newly added claim 26 directed to a method for producing viral particles has

adequately addressed and/or rendered this ground for rejection moot and respectfully ask that it be withdrawn.

Canceled claim 20 is by implication free and clear of the combination of Michel et al. and Wang et al. Applicants have now incorporated the limitations of canceled claim 20 and canceled claim 15 into new claim 26 which is now deemed free and clear of the combination of Michel et al. and Wang et al.

As admitted by the Examiner on page 8 of the Office Action, "Michel et al. and Wang et al. do not disclose the method step of isolation of HCMV viral particles from infected cells." That being the case, it is respectfully requested that this ground for rejection be withdrawn.

Claims 15, 17, and 18 stand rejected under 35 U.S.C. § 103 as allegedly obvious over Michel et al. (1996) in view of Wang et al. (US 5,830, 727) and further in view of Uyttersprot et al. (1998).

The Examiner asserts that Uyttersprot et al. discloses the lipid formulation, FuGENE 6 transfection reagent. While not admitting the Examiner's characterization of the teachings of Uyttersprot et al., Applicant points out that the subject matter of canceled claim 20 which is deemed free and clear of Uyttersprot et al., is now incorporated into new claim 26 and its dependent claims making new claims 27 and 28 patentable over Uyttersprot et al. Accordingly, it is requested that this ground for rejection be withdrawn.

Claim 20 stands rejected under 35 U.S.C. § 103 as allegedly obvious over Michel et al. (1996) in view of Wang et al. (US 5,830, 727) and further in view of Irmiere et al. (1983).

The Examiner asserts that Michel et al. discloses an HCMV gene with the N-terminal region of UL97 deleted but does not disclose transfected mammalian cell line which expresses the deleted HCMV gene so that the deleted HCMV can replicate in the cells. To cure Michel et al.'s deficiency, the Examiner imports the teachings in an entirely heterologous viral system – namely that of Herpes Simplex Virus wherein Wang et al. allegedly discloses the technique of isolation and propagation of deletion mutant HSV in a cell line transfected with complementing levels of the deleted essential gene of the viruses.

Regarding the subject matter of canceled claim 20, not taught either by Michel et al., or Wang et al., namely the isolation of subviral particles released after the infection of mammalian cells with HCMV wherein the particles contain neither DNA nor capsids and are surrounded by a lipid membrane in which viral glycoproteins are embedded, the Examiner asserts that Irmiere et al. disclose the isolation and characterization of the noninfectious virion-like particles from human foreskin fibroblasts. Applicants disagree and now traverse as follows:

The combination of Michel et al. and Wang et al. is improper. Michel et al. merely presented results tending to show that the deletion of the UL97 gene makes the deleted HCMV replication incompetent. Because Wang et al. uses an entirely different viral system, it at best is a principle and the mere fact that a process utilizes a known scientific principle does not alone make the process obvious. Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 5 USPQ2d 1434 (Fed. Cir. 1988). Cert. denied. 488 U.S. 825 (1988).

Further, the consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that the process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art...Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's

disclosure. In re Dow Chemical Co. 837 F.2d 469, 5 USPQ2d 1529 (Fed. Cir. 1988). In fact, to draw on hindsight knowledge of the patented invention, when the prior art does not contain or suggest that knowledge: is to use the invention as a template for its own reconstruction. Seasonics, Inc. v. Aerosonic Corp., 81 F.3d 1566, 38 USPQ2d 1551 (Fed. Cir. 1996).

To that extent, Applicant finds the asserted combination of Michel et al. and Wang et al. extremely problematic and improper since a close reading of both art does not suggest the invention herein claimed or the likelihood of success. Mere teaching by Michel that a deletion of a gene in HCMV makes the virus replication incompetent does not in anyway suggest the present invention directed to generating non-infectious viral particles for use as vaccines.

In view of that, Applicant respectfully contends that this combination is improper and requests that it be withdrawn.

Claims 21 and 22 stand rejected under 35 U.S.C. § 103 as allegedly obvious over Gibson et al. (1984) in view of Wills et al. (1996). According to the Examiner, Wills et al. disclose pp65 and other proteins as having cytotoxic T lymphocytes (CTL) epitopes and thus it would have been prima facie obvious to combine the teachings of Gibson et al., and those of Wills et al., to arrive at the invention of new claim 31 which incorporates the subject matter of canceled claims 21 and 22. Applicants disagree and now traverse as follows.

The Examiner's basis for rejection is predicated on his presumed teaching of a pp65-IE1 "fusion protein" of Wills et al. (Office Action, Page 9, Paragraph 6). After a close reading of Wills et al. Applicant found no teaching or suggestion of a fusion protein comprising pp65, neither did Applicant find any teaching or suggestion to incorporate that fusion protein into viral particles which contain neither viral DNA nor capsids, neither is it obvious that a fusion protein

of pp65 and IE1 will contain sufficient CTL epitopes. As such, not only is the combination asserted by the Examiner improper, the alleged combination still would not arrive at the invention of new claim 31, for at least the reason that Wills et al. neither taught nor suggested the use of fusion proteins, let alone fusion proteins comprising pp65, let alone incorporating such fusion proteins into sub-viral particles.

Accordingly, it is respectfully requested that this ground for rejection be withdrawn.

Conclusion

In view of the foregoing remarks, Applicants submit that there is no basis for applying the previous rejections to the pending claims and withdrawal of the rejections is respectfully requested. The claims are believed to be in condition for allowance, and Applicant earnestly solicits from the Examiner early notification of allowability.

Should the Examiner have any questions or believe a personal or telephonic interview may be in order, he is invited to contact the undersigned at his earliest convenience.

Respectfully submitted,

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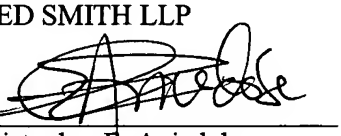
By: 
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